

APPENDIX- Pending Claims

1. A method for determining the concentration of a specific lipoprotein, an apolipoprotein, or lipid associated with a specific lipoprotein, in a biological sample comprising:

immersing into the sample a solid phase material having immobilized thereon antibody molecules immunoreactive with a specific lipoprotein or apolipoprotein;

allowing the antibody molecules time to bind to the lipoprotein or apolipoprotein in the sample;

removing the solid phase material containing the immobilized antibody molecules; and
determining the amount of lipoprotein, apolipoprotein, or lipid associated with a lipoprotein bound by the immobilized antibody molecules.

2. The method of claim 1 wherein the antibody molecules immobilized on the solid phase material are immunoreactive with a lipoproteins selected from the group consisting of HDL, LDL, VLDL, and combinations thereof.

3. The method of claim 2 wherein the antibody is selected from the group consisting of monoclonal antibodies, recombinant antibodies, and antibody fragments.

4. The method of claim 3, wherein the antibody is the anti-LDL monoclonal antibody produced by the hybridoma cell line HB₃cB₃ ATCC designation number HB 11612.

5. The method of claim 3, wherein the antibody is a recombinant anti-LDL RcB₃M₁D₄ ATCC designation number 69602.

6. The method of claim 1 wherein the amount of lipoprotein, apolipoprotein lipid is determined by staining of the material bound to the immobilized antibody using a lipid stain.

7. The method of claim 6 wherein the lipid stain is selected from the group consisting of Sudan Red 7B, Oil Red O, and Sudan Black B.

8. The method of claim 6 wherein the lipoprotein lipid is stained prior to immersing the immobilized antibodies.

9. The method of claim 6, further comprising antibody immunoreactive with apolipoprotein which is coupled to a protein stain and used to stain lipoprotein in the sample, prior to immersing into the sample the immobilized antibodies which then bind to the stained antibody-bound apolipoprotein.

10. The method of claim 1, wherein the apolipoprotein is selected from the group consisting of Apo A-I, Apo A-II, Apo B, Apo C-III, and Apo E.

11. The method of claim 1, wherein the biological sample is selected from the group consisting of blood, plasma, and serum.

12. A method of determining the concentration of an apolipoprotein in a biological sample comprising:

mixing an antibody immunoreactive with a specific apolipoprotein into the sample;
allowing the antibody to bind to the apolipoprotein in the sample,
immersing into the mixture a second immobilized antibody immunoreactive with a second, distinct epitope of the apolipoprotein,
allowing the second immobilized antibody to bind to the apolipoprotein,
detecting the presence of the apolipoprotein bound by both antibodies, and
determining the amount of apolipoprotein bound by both antibodies.

13. The method of claim 12 wherein the apolipoprotein is apolipoprotein Apo B-100.

30. A method for making a composition comprising
immobilizing on a solid phase material antibody molecules immunoreactive with a specific lipoprotein or apolipoprotein, wherein the antibody molecules are selected from the group consisting of monoclonal antibodies, recombinant antibodies, and fragments thereof.

31. The method according to claim 30 wherein the antibody molecule is specifically immunoreactive with LDL.

32. The method of claim 30 wherein the apolipoprotein is selected from the group consisting of Apo A-I, Apo A-II, Apo B, Apo C-III, and Apo E.